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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,

Plaintiff,

v.

YA FENG TRADING INC., LINMIN YANG,
and KONG PING NI,

Defendants.

CONSENT DECREE

No. 23 Civ. 6459

WHEREAS, on July 26, 2023, Plaintiff the United States of America (the “United States”), acting on behalf of the United States Department of Agriculture (“USDA”), filed a complaint for injunctive relief (the “Complaint”) against Defendants Ya Feng Trading Inc. (“Ya Feng”), Linmin Yang, and Kong Ping Ni (collectively, “Defendants”) alleging that Defendants have violated the Federal Meat Inspection Act (“FMIA”), 21 U.S.C. § 601 *et seq.*, and the Poultry Products Inspection Act (“PPIA”), 21 U.S.C. § 451 *et seq.*;

WHEREAS the United States and Defendants (collectively, the “Parties”) agree, and the Court by entering this Consent Decree finds, that this Consent Decree is fair, reasonable, and in the public interest; and

NOW, THEREFORE, with the consent of the Parties, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action pursuant to 21 U.S.C. § 467c, 21 U.S.C. § 674, and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all the Parties to this action.

2. Venue is proper pursuant to 28 U.S.C. § 1391(b) and (c).

ADMISSIONS

3. Defendants admit, acknowledge, and accept responsibility for the following:

- a. Until December 2022, Defendant Ya Feng operated as a wholesale distributor of meat and poultry products and a corporation organized under the laws of the State of New York with a principal place of business located at 23 Allen Street, New York, New York 10002.
- b. Defendant Linmin Yang is the president and sole owner of Ya Feng and held that position when the violations alleged in the complaint occurred.
- c. Defendant Kong Ping Ni was employed by Ya Feng as a warehouse manager when the violations occurred.
- d. Defendants have engaged in the business of selling meat, meat food products, poultry, and poultry products in the State of New York and within the jurisdiction of this Court.
- e. On several occasions between December 2018 and April 2022, Defendants sold, transported, and/or offered for sale and/or transportation misbranded meat, meat food products, poultry, and/or poultry products and/or failed to maintain records regarding their business transactions. Specifically:
 - i. On or about December 13, 2018, Ya Feng sold 20 pounds of misbranded chicken gizzards.
 - ii. On or about January 28, 2020, Ya Feng offered for sale and transportation 80 pounds of misbranded pork spare rib product and failed to maintain records that fully and correctly disclosed all business transactions involving meat in its business.

- iii. On or about November 9, 2020, and on other dates, Ya Feng offered for sale and transportation 5 pounds of misbranded chicken gizzards and 117 pounds of misbranded meat products (pork spareribs, pork fat, pork feet).
- iv. On or about November 30, 2021, Ya Feng offered for sale and transportation approximately 600 pounds of misbranded whole chickens, bone-in chicken thighs, chicken drumsticks, and chicken leg quarters.
- f. On or about April 14, 2022, USDA Food Safety and Inspection Service (“FSIS”) investigators visited the Ya Feng warehouse facility and observed 43,771.75 pounds of meat and poultry products being held in insanitary, rodent-infested conditions. Fresh and old rodent droppings were observed throughout the building, including in a walk-in freezer and walk-in cooler that held meat and poultry products. Droppings were observed on the lids of meat and poultry product boxes and beneath pallets holding the products. Some products had gnawing and chewing marks from rodents. Rodent nesting materials and a dead mouse were found in the walk-in freezer.
- g. Also, on or about April 14, 2022, Ya Feng offered approximately 280 pounds of misbranded poultry products for sale.
- h. Accordingly, Defendants have repeatedly violated the FMIA and PPIA.

REPRESENTATIONS BY DEFENDANTS

4. As a condition of entry of this Consent Decree, Defendant Ya Feng represents and warrants, under penalty of perjury pursuant to 28 U.S.C. § 1746, that:

- a. In December 2022, Ya Feng ceased any activity involving meat or poultry retailing or distribution or any activity otherwise governed by the FMIA and the PPIA.
- b. Ya Feng stopped this activity because of the risk of enforcement action by the USDA relating to violations at issue in this case.
- c. Ya Feng has no intention to resume such activity.
- d. Ya Feng is in the process of dissolving as a corporate entity.

5. As a condition of entry of this Consent Decree, Defendant Linmin Yang represents and warrants, under penalty of perjury pursuant to 28 U.S.C. § 1746:

- a. Since December 2022, Yang has not engaged in any activity involving meat or poultry retailing or distribution or any activity otherwise governed by the FMIA and the PPIA and has not owned, worked for, or had influence or control over a business engaged in such activity.
- b. Yang has no intention to engage in such activity or to own, work for, or have influence or control over any business engaged in such activity in the future.
- c. Yang does not own, work for, or have influence or control over the business currently operating at 23 Allen Street, New York, New York.
- d. Yang intends to obtain the corporate dissolution of Ya Feng.

6. As a condition of entry of this Consent Decree, Defendant Kong Ping Ni represents and warrants, under penalty of perjury pursuant to 28 U.S.C. § 1746:

- a. Ni ceased working for or having any affiliation with Ya Feng no later than December 2022.
- b. Ni worked for the business, which is unaffiliated with Ya Feng, that began operating at 23 Allen Street, New York, New York, after Ya Feng stopped operating there.
- c. In that subsequent position, Ni engaged in activities involving meat and poultry retailing and distribution, which are governed by the FMIA and the PPIA
- d. Ni's employment with the business operating at 23 Allen Street will not extend beyond July 31, 2023, and, after that date, he will no longer engage in activity involving meat or poultry retailing or distribution or otherwise governed by the FMIA and the PPIA.
- e. Ni has no intention to engage in such activity or to own, work for, or have influence or control over any business engaged in such activity in the future.

7. Defendants acknowledge that the United States has relied on the representations in Paragraphs 4 to 6 (including subparagraphs) in entering into the Consent Decree. Such representations are material to the United States' decision to agree to the terms contained herein. Accordingly, the United States reserves its right to seek additional relief from Defendants with respect to the matters contained in the Complaint if the representations in Paragraphs 4 to 6 are

inaccurate or contain omissions in any respect. Any such relief would be in addition to, and not in lieu of, the terms of this Consent Decree. Defendants waive any statute of limitations defense that may otherwise apply to such additional relief and acknowledge that this Consent Decree does not bar such additional relief.

INJUNCTIVE RELIEF

8. ***Three Year Bar (Ya Feng and Yang).*** Until three years after the Effective Date of the Consent Decree, Ya Feng—to the extent it is not dissolved—and Yang will not engage in or have any affiliation (including employment) with any business that engages in activity that is subject to the FMIA and/or PPIA, including but not limited to conducting any operations involving meat or poultry retailing or distribution.

9. If either Ya Feng or Yang violates the terms of Paragraph 8, the Defendant committing the violation will be liable to the United States for a stipulated penalty equal to the sum of (i) \$1,000 per day that this provision is violated, (ii) all profits obtained by the Defendant through the violations, and (iii) the United States' costs of investigating and taking enforcement action related to the violations (including costs incurred by the USDA). Any such penalties will be paid within 30 days of demand for payment by the United States without further action of the Court.

10. After the three-year period set forth in Paragraph 8 above, Ya Feng and Yang may submit a written notice to the United States stating an intent to resume engaging in, or affiliating with a business that engages in, activity subject to the FMIA and/or PPIA, including but not limited to conducting any operations involving meat or poultry retailing or distribution. Such notice shall state, under penalty of perjury pursuant to 28 U.S.C. § 1746, that such Defendant has the intent and ability to comply with the requirements of this Consent Decree. Such notice shall

be accompanied by any supporting information necessary to demonstrate such intent and ability. If the United States concludes that the supporting information and other available evidence demonstrates such intent and ability, it shall approve the notice and the Defendant may commence such activity thereafter, subject to the terms of this Consent Decree. If the United States concludes that the supporting information and other available evidence does not demonstrate such intent and ability, it may disapprove the notice. If the United States disapproves the notice, the Defendant may challenge this disapproval by motion to the Court and shall have the burden of proving that it has such intent and ability.

11. ***Mandatory Training (All Defendants).*** Before resuming any activity that is subject to the FMIA or the PPIA, Defendants and any of their employees must complete training and education in the FMIA and PPIA statutes and regulations, including requirements regarding labeling, sanitation, food safety, and product handling. Defendants must submit a written description of the training and educational program they propose to implement, along with a copy of all training and educational materials, delivery methods, and training schedules, no later than twenty (20) days prior to conducting such training and instruction to the FSIS Enforcement Operations Staff (“EOS”) Director for review and approval. Defendants must implement this training for all new employees within five (5) working days of their commencement of employment. Defendants and their employees must complete this training on an annual basis and ensure that adequate records of such training and educational programs are available to FSIS personnel for review and/or copying immediately upon request. This paragraph shall apply to Defendant Ni after July 31, 2023, when his employment with the business presently operating at 23 Allen Street ends.

12. ***Rodent Control (Ya Feng and Yang).*** If Defendants Ya Feng or Yang resume activity subject to the FMIA or PPIA, they will ensure that such activity complies with the pest control guidelines outlined in Sections 2.1 to 2.6 of the National Pest Management Association's publication *2016 Pest Management Standards for Food Processing and Handling Facilities* ("Pest Management Standards"), a copy of which is annexed hereto as Exhibit A. Defendants will also maintain a contract with an independent pest control contractor who agrees, in writing, to implement a rodent management program that is consistent with the Pest Management Standards. Defendants also agree to take all necessary steps to eliminate the presence of rodents in the facility, and ensure that:

- a. the pest control contractor surveys the interior and exterior of the relevant facility and familiarizes itself with the facility's rodent history, consistent with Sections 2.1 to 2.3 of the Pest Management Standards;
- b. the pest control contractor reviews and services the facility's interior on at least a weekly basis and exterior on at least a monthly basis, consistent with Section 2.4 of the Pest Management Standards;
- c. the pest control contractor implements an effective program to manage and monitor rodents at the facility, consistent with Sections 2.5 and 2.6 of the Pest Management Standards;
- d. the pest control contractor provides Defendants with written reports, detailing findings, recommendations, and any corrective actions or treatments performed and that Defendants maintain these reports for the duration of this Consent Decree and provide them to representatives of the USDA upon request;
- e. the recommendations of the pest control service contractor are implemented promptly and, in any event, no later than one week after the recommendation is made; and
- f. the rodent management program of Defendants is sufficient to prevent the creation of insanitary conditions arising from the presence of rodents and to ensure that meat and poultry products held for sale or storage, offered for sale or transportation, or received for transportation, are not contaminated or adulterated as a result of the presence of rodents.

13. ***Monthly Audit of Pest Control Measures (Ya Feng and Yang).*** If Defendants Ya Feng or Yang resume activity subject to the FMIA or PPIA, in addition to contracting with an independent pest control contractor as provided in paragraph 12, they will retain an outside inspector who has experience in the areas of food safety and pest control, and who has no connection to either Defendants or to the pest control contractor, to inspect the facility and to audit and assess the facility's rodent management program. The outside inspector will provide monthly written reports to Plaintiff and the applicable Defendant that describe in detail any inadequacies in Defendant's rodent management program and any evidence of rodents at the facility. The outside inspector will also assess whether Defendant's rodent management program is consistent with Sections 2.1 to 2.6 of the Pest Management Standards and industry best practices. Defendant will ensure that it and the pest control contractor review and implement any recommendations of the outside rodent inspector. Defendant will maintain the outside inspector's monthly reports for the duration of this Consent Decree. Before retaining the outside inspector, Defendant will provide the United States with a detailed summary of the outside inspector's credentials so that the United States may ensure that the inspector has the proper credentials. The United States must approve Defendant's retention of the outside inspector and, in no event will Defendant terminate or replace the outside inspector without prior approval of the United States.

14. ***Access; Seizure (Ya Feng and Yang).*** If Defendants Ya Feng or Yang resume activity subject to the FMIA or PPIA, they must, at all reasonable times, afford duly authorized representatives of the USDA full access to Defendants' establishment, if operating pursuant to a FMIA or PPIA Inspection Exemption. "Full access" includes full and unimpeded opportunity to inspect and examine Defendants' establishment or facility, operations, equipment, inventory, and records; to copy all such records; and to take reasonable samples of inventory. "All reasonable

times” means any hours during which Defendants are doing business at Defendants’ establishment, including hours before dawn where applicable. Additionally, authorized representatives of the USDA shall have the right to seize and destroy any and all misbranded or uninspected meat, meat food products, poultry, or poultry products in accordance with applicable laws, regulations, and FSIS directives.

15. ***Compliance with FMIA and PPIA (All Defendants).*** Without limiting the provisions of Paragraphs 8 to 10, Defendants and any of their directors, officers, agents, servants, representatives, employees, successors, or assigns, and any and all persons in active concert or participation with them, directly or indirectly, who received actual notice of this Consent Decree by personal service or otherwise, are hereby permanently restrained and enjoined from:

- a. selling, transporting, offering for sale or transportation, or receiving for transportation, any meat, meat food products, poultry, or poultry products required to be inspected and passed by the USDA that have not been inspected and passed by USDA federal inspectors;
- b. causing any meat, meat food products, poultry, or poultry products, capable of use as human food, to be misbranded while they are being transported in commerce, or within the designated state of New York, or being held for sale after such transportation;
- c. selling, transporting, or offering for sale or transportation adulterated, misbranded, or unlabeled meat, meat food products, poultry, or poultry products, or any meat, meat food products, poultry, or poultry products that do not meet FMIA’s or PPIA’s labeling and container standards;
- d. preparing, processing, holding, or storing meat, meat food products, poultry, or poultry products in unsanitary conditions;
- e. engaging in any other conduct that would violate the FMIA, the PPIA, and/or the regulations promulgated thereunder.

16. ***Compliance with Regulations (All Defendants).*** Without limiting the provisions of Paragraphs 8 to 10, Defendants agree to comply at all times with all applicable requirements of

regulations promulgated under the FMIA and PPIA and Title 1, Part 271 of the Official Compilation of Codes, Rules & Regulations of the State of New York.

17. ***Recordkeeping (All Defendants).*** Without limiting the provisions of Paragraphs 8 to 10, Defendants must maintain, for each product containing meat, meat food products, poultry, or poultry products, business records of all transactions by them, which fully and correctly disclose the purchase, receipt, offer for sale, sale, and transport of such products. Such business records shall include, but are not limited to, documents showing the amounts of meat, meat food products, poultry, or poultry products purchased by Defendants and receipts for such purchases and the amounts of meat, meat food products, poultry, or poultry products sold by Defendants to customers and receipts for such sales, as well as such other records set out at 9 C.F.R. §§ 320.1, 381.175. Defendants must maintain each record for a period of not less than three (3) years from the date of origination of such record. These records must be produced on request by the United States. This paragraph shall apply to Defendants only if they resume engaging in any activity involving meat or poultry retailing or distribution or any activity otherwise governed by the FMIA and the PPIA. This paragraph shall apply to Defendant Ni only after July 31, 2023, when his employment with the business presently operating at 23 Allen Street ends, and only to the extent that Ni has control over recordkeeping practices for any business at which he is employed that engages in conduct subject to the FMIA and PPIA.

18. ***Federal Grant of Inspection (All Defendants).*** Without limiting the provisions of Paragraphs 8 to 10, in the event that Defendants perform or intend to perform operations that require a federal grant of inspection under the FMIA or the PPIA, in order to be issued a grant of federal inspection and commence operations under such grant, including slaughtering, preparing, processing, selling, transporting, offering for sale or transportation, or receiving for transportation

poultry or poultry products, Defendants must demonstrate, subject to review and verification by FSIS, compliance with all FSIS statutory and regulatory requirements, including but not limited to 9 C.F.R. Parts 381, 416, 417, and 418. FSIS's review and verification will include an examination of Defendants' establishment, facilities, operations, and equipment, as well as Defendants' written Hazard Analysis and Critical Control Point program, Sanitation Performance Standards, Sanitation Standard Operating Procedures, and other food safety programs required by FSIS regulation.

19. ***Business Changes (Ya Feng and Yang).*** Defendants Ya Feng and Yang shall notify the United States in writing at least twenty (20) days before any change or cessation in ownership or character of Ya Feng. This includes assignment or sale resulting in the creation or emergence of a successor corporation or business entity, the creation or dissolution of subsidiaries, change or alteration of the business form or name, or any other change in their business structure that may have an effect upon Defendants' compliance with the terms of this Consent Decree. No transfer of ownership or operation of Ya Feng shall relieve Defendants of their obligation to ensure that the terms of the Consent Decree are implemented, and at least twenty (20) days prior to any such transfer, Defendants shall provide a copy of this Consent Decree to the proposed transferee.

20. ***Related Entities; Other Operations (All Defendants).*** By signing this Consent Decree, each Defendant certifies that that Defendant has disclosed to counsel for the United States any business entity engaged in meat, meat food products, poultry, or poultry products retailing, distribution, processing, or sale in which that Defendant has an ownership interest or an operational role. In the event that, after the execution of this Consent Decree, a Defendant acquires an additional ownership interest or begins an additional operational role in a business entity engaged in meat, meat food products, poultry, or poultry products retailing, distribution, processing, or sale,

such Defendant will notify counsel for the United States of such the business entity and interest or role within fifteen (15) days.

21. ***Violation of Sale Requirements (All Defendants).*** If Defendants fail to comply with the applicable restrictions of Paragraph 15(a)–(d) of this Consent Decree, Defendants agree to the following relief:

- a. for the first violation, Defendants agree to pay to the United States a civil penalty of \$500.00 per pound, or portion thereof, of meat, meat food products, poultry, or poultry products sold, transported, and/or offered for sale and/or transportation;
- b. for every violation thereafter, Defendants agree to pay to the United States a civil penalty of \$1,000.00 per pound, or portion thereof, of meat, meat food products, poultry, or poultry products sold, transported, and/or offered for sale and/or transportation.

22. ***Violation of Other Requirements (All Defendants).*** If Defendants fail to comply with any applicable requirement of the FMIA or PPIA and their regulations or with the requirements of this Consent Decree other than violations of the restrictions under Paragraphs 8–9 and 15(a)–(d)—including, but not limited to, violations of Paragraph 15(e) and Paragraph 17, Defendants agree to the following relief:

- a. Defendants agree to pay to the United States a civil penalty of \$500.00 per violation per day through the 14th day of violation;
- b. Defendants agree to pay to the United States a civil penalty of \$1,000.00 per violation per day from the 15th day of violation through the 30th day of violation; and
- c. Defendants agree to pay to the United States a civil penalty of \$2,500.00 per violation per day on or after the 31st day of violation.

23. ***Serious or Repeat Violations (All Defendants).*** The amounts set forth in Paragraphs 21 and 22 shall be separate and apart from any other remedy that the United States may pursue for violations of this Consent Decree. Should enforcement proceedings beyond this

Consent Decree be necessary, Defendants agree that the United States shall be entitled to recover from Defendants all reasonable costs and expenses incurred by the FSIS in any future enforcement proceedings, including investigation time, preparation time, and reasonable attorneys' fees.

24. ***Judicial Review (All Defendants).*** If Defendants disagree with a determination made by USDA pursuant to Paragraphs 21 to 23 of this Consent Decree, they may petition the Court for an independent review of USDA's determination(s). Any such petition must be filed within thirty (30) days of USDA's determination(s) for which review is sought. In reviewing USDA's determination(s), the Court will apply the same standard of review applicable to review of final agency action under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* Review shall be based exclusively on the written record before the USDA at the time the decision was made. No discovery shall be taken by either party. In the absence of a timely petition for review, USDA's determination(s) will become final and unreviewable. Defendants shall be liable for such relief as the Court deems appropriate in a proceeding brought either *sua sponte* or by the United States, for any failure to comply with any terms of this Consent Decree.

25. ***Other Rights and Remedies (All Defendants).*** This Consent Decree does not limit any rights or remedies available to the United States for any violation of the FMIA or PPIA and their associated regulations, or any rights or remedies available to the United States for any criminal violations. Defendants hereby waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to violations of this Consent Decree that may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment to the Constitution, the Excessive Fines Clause of the Eighth Amendment to the Constitution, any statute of limitations, or the doctrine of laches, this Consent Decree bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph

or any other provision of this Consent Decree constitutes an agreement by the United States concerning the characterization of payments from Defendants to the United States for purposes of the Internal Revenue laws, Title 26 of the United States Code.

26. ***Future Regulatory or Administrative Actions (All Defendants).*** The Parties agree that nothing in this Consent Decree shall preclude any future regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

27. ***Contempt (All Defendants).*** Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its reasonable attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

28. ***Termination (All Defendants).*** After Defendants Ya Feng or Yang have maintained continuous satisfactory compliance with all requirements of this Consent Decree, as well as all applicable provisions of the FMIA and PPIA, for a period of five years, that Defendant may serve upon the United States a request for termination of the Consent Decree as to that Defendant ("Request for Termination"), explaining how the Defendant has satisfactorily complied with all such requirements, together with all necessary supporting documents. The United States and the Defendant shall thereafter confer informally concerning the Request for Termination and any disagreements as to whether the Defendant has satisfactorily complied with the requirements for termination of the Consent Decree. If the United States agrees that the Consent Decree may be terminated, the United States and the Defendant shall submit, for the Court's approval, a joint

stipulation terminating the Consent Decree. If the United States does not agree that the Consent Decree may be terminated as to that Defendant, the Defendant may file a motion with this Court seeking relief from judgment pursuant to Rule 60(b) of the Federal Rules of Civil Procedure, provided, however, that the Defendant will not file any such motion until sixty (60) days after service of the Request for Termination on the United States. The Defendant must bear the burden of demonstrating to the Court that the Defendant has maintained continuous satisfactory compliance for the six-year period and that there is good cause to terminate the Consent Decree under Rule 60(b) as to that Defendant. This paragraph will apply to Defendant Ni, as well, except that the relevant period of continuous satisfactory compliance for Ni will be three years.

29. ***Provision of Copies; Declaration of Compliance (Ya Feng and Yang).*** Defendant Ya Feng must provide a copy of this Consent Decree to any of Ya Feng's officers, directors, and employees within ten (10) days of the date of entry of this Consent Decree and must promptly thereafter provide undersigned counsel for the United States with a sworn declaration of compliance that contains the information set forth below. Moreover, if Defendants Ya Feng or Yang become involved in any other meat or poultry retailing or distribution business or any business that otherwise engages in activities that are subject to the FMIA and/or the PPIA, the Defendant must provide a copy of this Consent Decree to that other business's officers, directors, and employees before such involvement begins and must promptly thereafter provide undersigned counsel for the United States with a sworn declaration of compliance that contains the information set forth below. The sworn declaration must set forth the fact and manner of compliance with this paragraph and must identify the name and position of each person to whom a copy of this Consent Decree was provided. If the person does not have a formal title, the sworn declaration must set forth after such person's name the function that such person performs.

30. ***Service.*** For purposes of this Consent Decree, service upon USDA (in particular the Enforcement Operations Staff Director) and the United States must be accomplished by overnight delivery using a private carrier, *e.g.*, Federal Express or United States Postal Service certified mail with return receipt, and shall be made to the following addresses:

For USDA:

United States Department of Agriculture
Food Safety and Inspection Service
Office of Investigation, Enforcement and Audit
Attention: Director, Enforcement Operations Staff
1400 Independence Avenue, Stop Code 3753
Washington, DC 20250

For the United States:

United States Attorney's Office
Southern District of New York
Attn: Assistant U.S. Attorney Mark Osmond
86 Chambers Street, 3rd Floor
New York, NY 10007

31. ***Payments.*** If Defendants are required to make any payment pursuant to this Consent Decree, Defendants will make such payment by electronic funds transfer pursuant to written instructions to be provided by the United States.

32. ***Effective Date.*** The provisions of this Consent Decree shall become effective immediately as to all Parties upon the earlier date of entry by the Court of the Consent Decree as an order of court or entry by the Court of a separate order approving the Consent Decree.

33. ***Jurisdiction.*** The Court retains jurisdiction to issue further decrees and orders as may be necessary to construe, carry out, modify, or enforce compliance with this Consent Decree.

34. ***Translation of Consent Decree.*** By signing below, counsel for Defendants certifies that he has explained each and every term of this Consent Decree to the Defendants Yang

and Ni in their native language(s), and Defendants hereby waive any defense or argument based on their failure to understand the terms of this Consent Decree before signing.

Dated: July 19, 2023
New York, New York

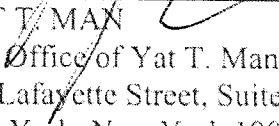
DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York
Attorney for the United States of America

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Dated: 7-13 2023
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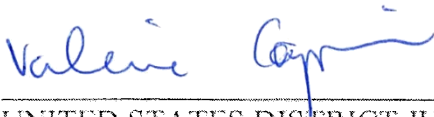
YA FENG TRADING INC.

By: Lin min yang
LINMIN YANG, President

Lin min yang
LINMIN YANG, in personal capacity

Kong Ping Ni
KONG PING NI, in personal capacity

SO ORDERED:


UNITED STATES DISTRICT JUDGE

Dated: 7/28/2023
New York, New York

The Clerk of Court is respectfully directed to terminate all deadlines and to CLOSE this case.



2016 PEST MANAGEMENT STANDARDS FOR FOOD PROCESSING & HANDLING FACILITIES



INTRODUCTION

The National Pest Management Association (NPMA) is pleased to release the *2016 Pest Management Standards for Food Processing and Handling Facilities*. Since 2007, NPMA guidance on pest management in food facilities has been the cornerstone of NPMA's commercial activities. These standards were last updated in 2013 and this 2016 version provides updates and improvements to better address changing regulatory requirements, new technologies and better integrated pest management practices.

The publication of this 2016 revision coincides with the implementation of the Food Safety Modernization Act (FSMA). FSMA will reform our food safety system by ensuring a safe food supply based on prevention rather than reaction. The new FSMA standards will bring increased scrutiny and oversight to the entire food industry which requires sanitation standards only achievable through proper pest management practices.

Of note in the 2016 revision the name was changed from Pest Management Standards for "Food Plants" to "Processing and Handling Facilities" to better reflect the intended scope of these standards. Other new additions include addressing the use of remote monitoring technology and the addition of a "sample risk assessment" that may be used as a reference to assist in analyzing, creating and maintaining a successful pest management plan. In the 2013 revision we moved away from prescriptive instructions regarding placement and monitoring frequency in favor of a results oriented approach based on trends, inspection and observations. The 2016 revision maintains this approach but provides some baselines in situations where historical data is unavailable.

These standards are general guidance for the industry and require the use of independent judgment when implementing a pest management plan in food processing and handling facilities. As stated in previous editions, these standards do not preempt local, state, or federal laws and regulations. Any service provided must comply with relevant statutes and regulations governing pest management, safety and food protection. In addition, food plants may have requirements more stringent than these standards.

To demonstrate understanding on these standards, NPMA maintains study materials and an online exam at www.npmatesting.com. Upon successful completion, the system generates a completion certificate. Printed study guides and standards can be purchased from NPMA at www.npmapestworld.org. Through online testing and food safety resources, NPMA is working to provide

the tools necessary for pest management firms to comply with the standards and raise the level of competency of pest management professionals servicing food plants.

We hope that you find these standards to be a beneficial resource for your organization. As protectors of food and property and defenders of public health it is our industry's obligation to exceed expectations and demonstrate the pest management industry's vital role in food safety.

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DEFINITIONS

For definition purposes,

Action Threshold means level of pest activity or pest damage that triggers a pest management response.

Company means the pest management firm

Contact means the food facility contact person

Current Good Manufacturing Practices means the FDA's Current Good Manufacturing Practices (CGMPs) in the United States, or equivalent outside of the U.S.

Devices any equipment used to monitor or control pests including, but not limited to, insect monitors, rodent bait stations, insect light traps, pheromone traps, and rodent management stations.

Employee means pest management firm employee

Facility is used interchangeably throughout these standards as the shortened version for "Food Processing and Handling Facility"

Food Processing and Handling Facility means any food facility engaged in food production, manufacturing, storing/warehousing and distribution. This does not include restaurants or other food service facilities.

Pest management product means any lure, bait, monitoring product, pesticide, or any other formulated material used in performance of pest management activities.

Rodent bait station means any station used for placement of solid rodenticide bait

Rodent management device means any device used for monitoring or managing rodents. These include mechanical traps, rodent bait stations (see above), and other placed equipment for rodent management.

Technician means the pest management firm employee providing service

We hope that you find these standards to be a beneficial resource for your organization. As protectors of food and property and defenders of public health it is our industry's obligation to exceed expectations and demonstrate the pest management industry's vital role in food safety.

SECTION 1

PERSONNEL

1.1 EMPLOYEE IDENTIFICATION

Both food security and safety are the primary concern of the food facility. This section sets forth minimum standards for company employee identification so that the facility has a clear understanding of which personnel are from the pest management company to ensure that facility food safety and security are maintained.

All employees entering grounds of a food facility shall display photo identification to include:

- Employee name
- Employee identification number (if issued by the company)
- Company name
- Company phone number
- Employee photo
- Date of issue

The identification shall be displayed at all times while the employee is on site unless personnel practices set by the facility prohibit such badges. In addition, facilities may require other identification such as visitor badges or facility issued contractor badges and the employee must comply at all times with the visitor/contractor policies of the facility.

1.2 UNIFORMS

Uniforms are an important part of the facility safety and standards program. Criteria are designed to comply with the majority of food facility requirements and CGMPs for uniforms.

All employees who perform service work in food facilities shall wear uniforms meeting current facility requirements and at least the following criteria:

- Slip resistant sole shoes (safety toe if required by facility)
- Socks
- Long pants
- Shirt with sleeves (short or long) with company logo or company name
- Uniform closures shall be in compliance with facility requirements.

A clean set of clothing shall be used in facilities. If the uniform is exposed to contaminants a clean set of clothing should be readily available. These contaminants include but are not limited to chemical, microbiological, or allergens such as peanut products.

More stringent requirements may be in place for individual facilities *in addition to these standards* and service personnel must comply with those standards. Some facilities may require the use of designated shoes, shoe covers, smocks and/or lint brushes prior to entering sensitive food processing areas.

1.3 SECURITY AND CRIMINAL BACKGROUND CHECKS

Security is a major concern at all food facilities. This section is designed to ensure that personnel in food facilities have had proper background checks and that they comply with facility rules.

Any newly hired employee, including management, entering a food facility shall have a criminal background check performed covering the previous five years prior to the date of hire. The checks shall be part of the records of the company and shall include all states or provinces in which the employee has lived and/or worked during the previous five years. Resulting action as a result of the check will be at the discretion of company management. Some food facilities may have specific requirements and companies must comply with these requirements in addition to the above. Reminder: Companies must comply with government regulations related to obtaining background checks.

Facilities may also have policies regarding when an employee is permitted onsite and if they require a facility escort. Companies should understand and comply with all facility policies and provide a written procedure to employees with a copy in the facility regarding:

- Whether advanced notice must be given prior to arrival onsite
- Parking and vehicle use
- Notice of new or substitute employees (technicians taking the place of previous technicians may have to be on a roster provided to the facility)
- Sign-in policies
- Hours of operation when employees may have access
- Visitor badge and/or contractor badge policies
- Confidentiality of facility information
- Escort policies
- Restricted areas
- Access to locked or restricted areas via an assigned key, card, fob, access code etc.

1.4 FACILITY PERSONNEL PRACTICES

It is imperative that all employees entering a food facility property understand and comply with facility personnel practices. Besides being required by law, compliance is important as part of food safety and also facility personnel morale.

Where applicable, all employees entering food facility property must have reviewed and signed off on the standards of the facility in terms of personnel practices as outlined by the facility. If a special set of standards is in place for facility contractors, then the employee must comply with the standards. If any questions or conflicts arise, the employee must notify their supervisor and the facility contact person.

A copy of the signed document shall be made available upon request.

1.5 VEHICLES

Facilities may have specific requirements for vehicles both in terms of operations and in terms of security. This section sets the minimum for vehicle standards.

All vehicles used for service must:

- Be clearly marked with company name
- Be properly licensed
- Have a current inspection if required by the state or province.
- Have adequate insurance coverage for bodily injury, property damage and any other coverage that may be required by the facility
- Be parked in properly assigned area
- Have materials and equipment secured when unattended to restrict access

A five year motor vehicle background check must be completed for all new company employees who will drive on facility property.

All drivers must have viewed the NPMA Safe Driving Video or participate in an insurance industry approved program annually and the company must retain safe driving training records as required by the insurance company.

- In addition, the vehicle must include at least the following equipment:
- First aid kit
- Spill control to cover all products on the vehicle
- Service kit (carrying kit for small quantities of products and equipment)
- Change of clothing and/or coveralls
- Other equipment required by facility

1.6 SAFETY

Safety is a vital part of any pest management program. The pest management company and the food facility both must maintain safe working environments.

Beyond minimal regulatory requirements, policies must be in place to ensure a safe work environment.

Each company must have a documented safety training of all employees working in food facilities. Safety training should include but is not limited to:

- Facility-specific safety training
- The company and facility specific respiratory protection program
- Pesticide safety including the proper understanding of all labels of products to be used in the food facility, proper use, and disposal of products and containers
- Proper storage of products and equipment
- Emergency response procedures in case of spills
- Safety of other personnel near pest management activities such as facility employees and the general public
- Ladder use and transportation safety
- Use of fall prevention equipment and lifts
- Slip and fall prevention
- Lock out and tag out systems
- Shoe safety
- Personal protective equipment
- Definition of accident
- Accident and injury reporting requirements
- Fumigation plan (if fumigation is to be performed) (Note: in general, fumigation is not covered by these standards)
- Restricted areas in facility
- Confined space entry requirements and their recognition
- Hazard communication

Note: An optional safety manual is available for sale through the NPMA Resource Center which addresses safety program compliance and will provide guidelines for developing a safety program. For more information visit www.npmapestworld.org.

1.7 MINIMUM TRAINING STANDARDS FOR TECHNICIANS

Any technician performing pest management services in food facilities must be trained. Proof of training must be available to the food facility contact.

These standards require pesticide certification or registration in compliance with law and verifiable training specific to food facility pest management including an exam regardless of whether an exam for the state or province has been passed for certification or registration of technicians.

Testing is conducted via the internet and is administered for a nominal fee by NPMA. Procedures and verification are the responsibility of NPMA.

NPMA has provided a testing site at www.npmatesting.com. A proctor designated by the company is required and the test is closed book. Each technician to be tested must establish his/her own account on the testing site and must select his/her own username and password. The login information is NOT the company's NPMA membership login.

There are fifty random questions on the exam and technicians must score 80% (40 correct) or better to pass. Technicians who do not pass may retake the exam at no additional cost.

An optional study guide is available through the NPMA Resource Center to provide education on food facility work and to help pass the exam. Not all questions are directly from the study guide. The testing site does provide advice on how to prepare for the exam at www.npmatesting.com.

1.8 COMPLIANCE WITH FOOD SAFETY RULES CGMPs

Federal agencies have established regulations to include basic food safety. Pest management professionals should be familiar with the food safety regulations including the Current Good Manufacturing Practices (CGMPs) and the Food Safety Modernization Act (FSMA) or equivalent in other countries.

All pest management programs must comply with CGMPs. All technicians performing any type of work in food facilities must be trained in requirements of CGMPs and facility implementation. Also, facilities may have additional food-safety related requirements beyond CGMPs and technicians must be trained in facility policies as well. Written verification of training must be on file in the facility and in the company office.

Typical food safety requirements for personnel include:

- Use of hair nets, beard guards or other hair restraints
- Removal of jewelry such as rings, watches and ear rings
- Washing and sanitizing hands and equipment prior to entering food processing areas
- Use of smocks or designated clothing which will help prevent the contamination of food or food contact surfaces

The updated CGMPs, located in Appendix C, specifies that pests must not be allowed in any area of the facility. Specifically, 21 C.F.R. § 117.35 states, "Effective measures must be taken to exclude pests from the manufacturing, processing, packing and holding areas and to protect against the contamination of food on the premises by pests." In order to protect clients from regulatory violations, the pest management program must be designed to identify food safety risks, and take effective measures through diligent pest proofing, monitoring and control. All steps must be well documented. The client/pest management professional partnership becomes even more critical in achieving pest prevention goals. The program outlined in these standards is designed to meet these requirements.

SECTION 2

PEST MANAGEMENT PLAN

2.1 RODENT PROGRAM – EXTERIOR PROPERTY SURVEY

Prior to developing a rodent management program at each facility site, a thorough inspection must be made. The exterior property of the property should be inspected and the following observations (at a minimum) must be identified and documented using a diagram and/or notes:

- Areas of rodent infestation based upon sightings, harborages, or other evidence including all areas of the building including roofs
- Areas of the property conducive to infestation such as cluttered areas, open trash, standing water, potential or confirmed burrowing areas
- Dumpsters which are not on rigid cleanable areas such as concrete pads
- Open doors or gaps in building areas which could permit rodent entry
- Clutter or debris underneath load levelers
- Dock areas that have clutter or debris
- Off loading areas with clutter or debris
- Tall grass and vegetation on property, sidings, and adjacent to buildings
- Perimeter areas of buildings having less than 24" of clearance and areas not having gravel or other material which will reduce chances of rodent activity
- Neighboring properties which may have conditions conducive to infestation

A summary of infestation observations and potential infestation must be documented and presented to the pest management contact of the facility.

2.2 RODENT PROGRAM – INTERIOR SURVEY

All areas of the facility interior shall be surveyed for rodents and conditions which may lead to rodent infestation. The following observations must be identified and documented using a diagram and/or notes:

- Open doors, gaps beneath doors, or other holes, gaps or cracks which could permit rodent entry
- Clutter, debris or other potential rodent harborage location
- Lack of 18-inch inspection aisle along walls
- Areas of rodent infestation based on sightings, droppings, harborage or other evidence
- Spillage or other potential food sources which could lead to infestation
- Storage practices which are conducive to rodent infestation

A summary of recommendations shall be provided to the pest management contact at the facility to reduce the likelihood of future infestations

Any rodent management devices shall be mapped and recorded.

2.3 RODENT PROGRAM – FACILITY HISTORY

Prior to designing and implementing a rodent management program, a company representative shall interview facility contacts and review all available rodent history information, including, but not limited to:

- Previous rodent management efforts
- Pest management records including rodent trend analysis
- Pest sighting data

2.4 RODENT PROGRAM – FREQUENCY OF SERVICE

Number, placement and frequency of inspection of rodent devices must be based on an assessment of the items outlined in sections 2.1, 2.2 and 2.3, including potential for infestation and facility history.

As a result of the initial inspection, examination of infestation history, and discussions with facility personnel the potential for infestation is determined. Based upon the potential for infestation the pest management program can be developed by the pest management company in cooperation with the facilities' management. If the facility is well sealed, and there is minimal chance of infestation by rodents, the potential for infestation is reduced. If contributing factors like exposed food material, potential entry points, or open doors on the building exterior, the potential for infestation is much higher.

FREQUENCY OF SERVICE – EXTERIOR AREAS

Inspection frequency is based on the company's evaluation of the facility's rodent history and potential for infestation. Minimum frequency of service conducted on exterior devices will be monthly. Should rodent activity occur, service frequency, if needed, will be increased.

Results of the rodent history and infestation potential analysis should be reviewed by and accepted by facility contact and may be reviewed and adjusted as necessary.

FREQUENCY OF SERVICE – INTERIOR AREAS

Inspection frequency is based on the company's evaluation of the facility's rodent history and potential for infestation. Minimum frequency of service on interior rodent monitoring devices will be weekly unless otherwise agreed upon with the customer. Appropriate documentation of any change from the weekly service schedule will be documented and maintained on file at the facility.

2.5 RODENT PROGRAM – SPACING OF RODENT MANAGEMENT DEVICES

SPACING OF RODENT MANAGEMENT DEVICES

Rodent populations in food processing and handling facilities exhibit dynamic behavioral characteristics. The placement of rodent monitoring devices must meet these challenges with flexibility based on inspection observations and known behavior of the species present. Establishing proactive preventive rodent monitoring programs in food processing and handling facilities is essential to prevent risk to food products and the health of consumers.

Proper placement of rodent management devices relies on a thorough assessment of the physical conditions of the facility and the presence of existing activity levels before an initial monitoring program can be established. Additionally, due to changing conditions, the program should be reviewed on a quarterly basis to ensure the needs of the facility continue to be met.

Record of service verification such as stickers, cards, or bar codes shall be on the inside of the device, requiring the device to be opened to record data or to scan.

Proper care must be exercised to comply with the label in terms of access by children or non-target animals. If it is not possible to install rodenticide bait stations in secure areas, glue boards, snap traps or other mechanical traps may be used inside of locked and anchored stations.

Monitoring stations may also be used with a non-toxic bait.

EXTERIOR RODENT MANAGEMENT DEVICES

Based on the target species, mechanical devices and/or tamper resistant bait stations will be installed in locations based on the risks identified through the assessment. Conditions identified, as increased or likely risk of rodent activity on the exterior require devices to be placed in locations likely to intercept the target rodent. Every effort must be made to work with the facility to eliminate conditions likely to attract rodents to the facility or provide access into the facility. All monitoring device placements must be in accordance with local, state and federal requirements.

If the previous 12 months of historical data is unavailable, or changing conditions make it difficult to determine the exterior rodent pressure at the time of the assessment, it is suggested an initial spacing placement of 50 to 100 feet. This placement would be established until the quarterly assessments and routine servicing of units can establish a baseline. The data collected during monthly service of devices will be used to determine and justify the number and location of the devices. Identification of high or significant activity should indicate a need for increased surveillance and possibly additional monitoring devices until activity is resolved.

PROPERTY PERIMETER

If an exterior property perimeter program is utilized, then based upon history, rodent management equipment, such as but not limited to rodent bait stations or multiple-catch traps, shall be placed along property perimeter areas (e.g. fence lines or outer boundaries) at intervals based on the professional judgment of the company and in accordance with rodenticide label instructions (if applicable).

EXTERIOR BUILDING AREAS (buildings at or near exterior walls of buildings on facility property)

Based upon history, rodent bait stations shall be placed along building exterior areas at intervals based on the professional judgment of the company in accordance with rodenticide label instructions (if applicable).

INTERIOR RODENT MANAGEMENT DEVICES

Based on the facility assessment and evidence of rodent activity, rodent monitoring devices appropriate for the species present will be installed in appropriate location and numbers to protect the food products from contamination. Every effort will be made to identify and eliminate conditions encouraging rodent activity within the facility.

Interior devices should be placed in locations determined to likely intercept rodents. Sensitive areas such as grade level doors, receiving doors and storage areas for products coming in directly from an exterior source should be considered as suspect when installing devices.

If the previous 12 months of historical data is unavailable or changing conditions make it difficult to determine the interior rodent pressure at the time of the assessment, it is suggested an initial spacing placement of 20 to 40 feet. Appropriate spacing adjustments will be made based on the data collected. Areas not demonstrating risk or conditions likely to attract and hold rodent activity, device spacing can be increased accordingly. Any evidence of activity or conditions increasing the risk of rodent activity, spacing will be decreased and additional devices installed as determined to be required to eliminate the activity and protect food products. All devices must be numbered and records must reflect the location of each placement.

Rodenticides shall not be used inside food facilities in any area unless approved by the facility contact and permitted by label. Upon such a request, any action and reasoning must be documented and should be temporarily used when there is no exposed food product. Non-toxic monitoring blocks may be used if permitted by facility contact.

Facilities should have an inspection aisle of at least 18 inches along walls. Commonly, this area is painted white or another light color in order to contrast with droppings or insects. Traps may be placed along these areas.

Due to concerns about allergens, no peanut butter or nut based attractants may be used inside a facility unless approved by facility contact.

2.6 RODENT PROGRAM – MONITORING

Adjustments to the program based upon observations may be made at any time. Use of “temporary” program changes are acceptable. All traps, bait stations, and other devices must be opened and inspected. Record of service verification or bar code shall be on the inside of the station requiring the station to be opened. Observations must be recorded as outlined in the Recordkeeping section.

All devices installed, permanent or temporary will be reflected on a site map, numbered and accounted for at each service. Devices will be inspected for activity, cleaned and the results documented at each service. Data collected on the rodent monitoring devices will be trended and the information provided to the facility IPM coordinator for appropriate action. Damaged devices will be documented and replaced at the time of service or at the earliest possible time.

Rodents must be disposed of offsite according to facility and company policy.

Rodents, droppings, and any urine deposits or residue must be handled using protective equipment per company policy.

2.7 REMOTE ELECTRONIC MONITORING TECHNOLOGY

Remote electronic monitoring technology for pest management devices provide an opportunity to use advancements in technology to improve the overall efficiency and effectiveness of pest management activities. As the technology evolves, science based reviews of the system confirm its value and customer acceptance expands; the devices should become an accepted tool. The structural pest management industry embraces proven advances in technology providing more effective and efficient IPM systems to meet our customer needs.

Remote electronic monitoring devices will be able to signal an event notification to the pest management provider and/or client. This type of information flow, if supported by accurate data, may enable pest management companies to redirect their efforts to other pest management actions. It is our belief that as the pest management industry gains more experience with this technology and the equipment is refined; it will permit greater flexibility in our ability to focus on the special pest management needs of a particular site. Pest management companies will need to determine on a case by case basis how often these devices need to be manually checked to maintain their functionality as part of the food safety program.

The National Pest Management Association views this technology as a viable addition to a sound science-based IPM strategy.

2.8 INSECT PROGRAM

INSPECTION

A thorough inspection shall be conducted of the exterior of the building including raw material receiving, receiving docks, shipping docks, load levelers, waste disposal, entrances, roof areas, exterior storage such as silos, doors and windows, and ventilation intakes to investigate signs of infestation or possible signs of infestation by insects.

A thorough inspection of the accessible components of the facility shall be conducted not less than monthly. The areas to be inspected include but are not limited to floor/wall junctures, drop ceilings, equipment, processing areas, warehousing materials and racking, offices, locker rooms, mezzanines, raw material handling and processing, returned goods areas, sample areas, windows, ventilation, shop areas, packaging storage and equipment, laboratory areas, and cafeteria.

In the course of the inspection, maintenance issues such as, but not limited to, holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted. Recommendations shall be made to the facility to reduce chances of future infestation.

A summary of infestation observations, potential infestations and recommendations for pest prevention shall be documented and presented to the facility's pest management contact.

ACTION THRESHOLDS AND CORRECTIVE ACTION

Corrective action will be taken, when appropriate, based on inspection, monitoring data and trend analysis in accordance with thresholds developed by the company in partnership with the facility.

STORED PRODUCT INSECTS

Determination of the source of stored product pests must be completed where possible. Sometimes, a certain lot of raw materials can be isolated as the source. If pests have spread into the facility, management measures must be performed.

Pheromones and pheromone traps may be used as part of the monitoring and management processes.

NON-STORED PRODUCT INSECTS AND OCCASIONAL INVADERS

Determination of source and entry point, real or potential, is necessary in developing a control/management program. Commonly, mechanical alterations on the exterior will be necessary such as filtering incoming air, sealing cracks, repairing door gaskets or self-closing doors, etc.

PESTICIDE/ PRODUCT USE

In the event it is necessary to apply a pesticide product to help manage insects the product shall be appropriately labeled for the intended use and site. These products may be residual, non-residual or non-regulated/exempt products.

An approved pest management product list should be developed by the company and approved by the authorized facility contact person.

Space treatment may be used to reduce adult populations. This may also include the use of insect growth regulators (IGRs).

General applications may be used only if the use of the product will not contaminate the food product.

After coordination with the facility contact fumigation may be considered as part of the management plan. These standards do not address fumigation specifically.

Insect bait stations may be used in areas not prone to heavy traffic or water accumulation.

Treatment of electrical panels and boxes must be done with extreme care per the label and liquids should not be used.

All pesticide products must be used according to label instructions.

INSECT LIGHT TRAPS AND OTHER FLYING INSECT TRAPS

Insect light traps (ILTs) may be installed to monitor and manage certain flying insects and to be used as part of the decision making process for adjusting the program for certain insects (e.g. Indian meal moths, fruit flies, etc.). Placement must be according to manufacturer's instructions and in compliance with any regulatory policies and guidelines. In absence of instructions, ILTs should be placed in such a manner that will maximize insect capture without:

- interfering with facility operations
- being visible from the exterior
- being likely to attract insects to open food

Any ILT must be recorded on the site layout or map, and ILTs must have the same recordkeeping as other types of devices.

Findings and seasonal requirements will dictate frequency of inspection as determined by the company. Insect traps must be monitored based upon the contract. Weekly monitoring is suggested for most cases, unless the traps are in an area or at a time of year when there is no activity (e.g. unheated warehouse or in cold winter climates).

The type of ILT will be determined based on the area of the facility, regulations and customer policy.

The trap must be cleaned in a manner that does not compromise product safety.

Trapped Insects must be examined and should be categorized according to:

- Stored product insects
- Structure infesting flies
- Other flying insects

The technician should determine if the types and numbers of insects exceed pre-established action threshold levels and if so, then the insect management program should be modified to address the issue.

Bulbs in ILTs must be changed according to manufacturer's recommendations or, in the absence of manufacturer's recommendations, annually. Shatter protection must be in place where food or packaging may become contaminated by glass.

Glue board style ILT must have glue boards replaced when the glue loses tackiness, or the number of insects caught exceeds the pre-established threshold levels. This replacement threshold should be determined with facility management as part of the pest management plan.

2.9 BIRDS AND WILDLIFE

Prior to the implementation of any bird or wildlife control program, consult local, state and federal laws and regulations regarding nuisance wildlife control.

Birds and wildlife can enter facilities or facility areas and create contamination or potential contamination hazards.

In the course of the inspection, maintenance issues such as but not limited to holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted. Recommendations shall be made to the facility to reduce chances of future infestation.

BIRD PREVENTION/MANAGEMENT

Areas susceptible to infestation by birds shall be called to the attention of the facility contact. If the facility approves, bird prevention measures may be installed. These shall be any type of wire, net, device, or material to prevent roosting.

Any interior bird removal shall be performed in accordance with local, state and federal laws and regulations. Use of protective gear shall be required for removal of nests and/or droppings.

Facilities should be encouraged to eliminate favorable conditions for bird infestation and observations by the technician shall be recorded in the log.

Within the confines of the above, additional information on bird management may be found in the NPMA Pest Management Library, available through the NPMA Resource Center (www.npmapestworld.org).

WILDLIFE PREVENTION/MANAGEMENT

Areas susceptible to infestation by wildlife shall be called to the attention of the facility contact. If the facility approves, wildlife prevention measures may be installed. These shall be any type of wire, net, device, or material to prevent entry, nesting, and/or roosting. This is usually beyond the scope of the original contract and a separate contract should be developed.

Any miscellaneous animal removal shall be by trapping and removal in accordance with local regulations. Exterior infestations such as prairie dogs on grounds may be managed by repellents or other method according to label or instructions. Use must be in accordance with manufacturer's instructions.

Facilities should be encouraged to eliminate favorable conditions for wildlife infestation and observations by the technician shall be recorded in the log.

Within the confines of the above, additional information on wildlife biology and management may be found in the NPMA Pest Management Library or the NPMA Resources Center www.npmapestworld.org.

2.10 WEED MANAGEMENT

Vegetation should not be planted against the buildings (exterior). An inspection band and clear zone adjacent to the building should be encouraged as part of the periodic audit. If the company performs weed management, ideally a vegetation free clear zone should be maintained.

This item shall be checked as part of the normal inspection process during pest management service regardless of whether the company performs weed management. Any vegetation around the building should be called to the attention of the facility contact for management in order to reduce the chances of infestation. Note: Certain types of vegetation/plantings may be more susceptible to pest harborage. These may be noted during the inspection.

2.11 PEST MANAGEMENT SURVEY

At least monthly, the pest management company shall perform an inspection to identify pests and the potential for infestation. Building maintenance, employee practices, physical conditions of the facility, incoming materials, processing, and shipping shall be evaluated. Recommendations shall be presented to the facility contact including the review of facility documents such as incoming materials inspection and pest sightings, and technician observations.

Forms shall be used to record observations and recommendations and a copy shall be disclosed to and signed by the facility contact.

Forms shall have one copy submitted to facility contact, one copy shall be filed with the pest management records and a copy shall be kept by the pest management firm unless the forms are filed and maintained electronically.

2.12 STORAGE – STANDARD NUMBER

All pesticides for use in pest management shall be stored off site or in a locked and secured storage area with adequate spill control and safety equipment for all materials stored. All storage must be in compliance with government regulations as well as the policies of the food facility. Any storage requirements listed on the label must also be addressed. If storage is in a locked cabinet, all room requirements must be met. Fumigants shall not be stored onsite unless storage requirements of the label are met.

Records must be stored in a secured area.

2.13 COMPLIANCE WITH FACILITY FOOD ALLERGEN CONTROL PROGRAM

Many consumers have acute reactions to food allergens. “Big Eight” allergens include: cow’s milk, eggs, peanuts, tree nuts, soybean products, wheat, fish, and crustacean shellfish. Consequently, facilities must declare if there is a possibility of any of these products entering the food either as an ingredient or an incidental additive. Facility policies and third party auditor standards may require formal food allergen control programs and these programs might affect pest management practices.

The pest management company must comply with any facility food allergen control program as it relates to pest management practices.

2.14 QUALITY ASSURANCE

At least once per year (prior to the anniversary of the date on which the company began pest management services at the food facility) a supervisor quality assurance staff person, or a manager from the pest management company shall review the entire program onsite and provide a quality assurance audit. The quality assurance audit shall include a review of the program, records, pest activity trends and frequency of service, as well as the monthly inspections to make sure that all documentation is in order. In addition, labels and Safety Data Sheets must be reviewed to make sure that all products used have current information. Safety Data Sheets and labels of pest management products used at that facility must be filed either in hard copy or via electronic records.

Results of the quality assurance audit must be filed in the facility, with a copy in the pest management company office.

2.15 ANNUAL TRAINING

At least once per year, the pest management company shall offer to conduct an educational program for facility personnel. Date, content, and list of those who attend must be kept in the facility pest management records.

The following staff should be encouraged to participate:

- Management
- Supervisory staff
- Security
- Mechanics
- Production lead staff
- Warehousing staff
- Quality Assurance staff
- Facility contact
- HACCP committee, if applicable
- Others to be determined by the facility management

While the facility manager ultimately makes the decision as to who may attend and the content, critical topics in line with current regulations, third party audit standards and general pest management program goals include:

- Review of the pest management program
- Vulnerable areas
- Practices which may reduce pest pressures
- Review of audits and monthly reports
- Pest exclusion
- How to record a pest sighting
- Review of FDA, state, provincial, local, and third party audits and inspections as related to pest management.
- How facility personnel should interact with pest management tools and devices

2.16 ANNUAL REVIEW

A review of the entire pest management plan should be performed on an annual basis and adjustments made as necessary.

The annual review shall include, but is not limited to:

- Thorough inspection of the exterior property
- Thorough inspection of the interior of the facility
- A summary of pest infestations and conditions conducive to infestation
- An analysis of pest trend data
- Results of the quality assurance audit

SECTION 3

COMMUNICATIONS

3.1 REPORTING

All documents in the pest management filing system must be available to the facility within a reasonable time as determined by the facility management. The facility management has the option of requesting copies of all documents produced including service tickets for their files. The pest management company must keep a backup copy of all documents at the pest management company office. The pest management company shall not surrender any copies of materials to any official without the express written permission of the facility contact or their substitute. If there is a regulatory audit of the pest management program conducted by the state department of agriculture or other pesticide enforcement agency, the pest management company may surrender documents to the agency if required.

While paper backup information may be permitted, official documentation and reporting listed in these standards shall be retained electronically in the following manner:

- Reporting shall provide access to all service data
- Record recovery shall be available on demand with the ability to be sorted by product used, area, pest, date, time, and shift.
- Assessments and trending reports shall be available

Data onsite may be gathered by handheld electronic devices or manually or a combination of these methods. Paper backup information may be permitted.

SECTION 4

RECORDKEEPING AND CONTRACTS

4.1 CONTRACTS

Prior to completing any work in a food facility, a signed contract must be available unless specifically waived by the food facility and must include:

- Name of facility
- Facility contact person
- Frequency of visits
- Description of services
- Term of contract
- Fee
- Scope of emergency calls
- Approved products/materials list
- Service records to be issued to the facility
- Requirement to notify facility of any new products used

4.2 LABELS AND SAFETY DATA SHEETS

A copy of all EPA, PMRA (Canadian Pest Management Regulatory Authority), or other country product labels and Safety Data Sheets for pest management products used at the facility shall be provided. These may also be filed electronically or web-based depending on facility policy and government regulations. Labels and Safety Data Sheets shall be added for any new approved products used.

4.3 PEST SIGHTING LOG

Each pest management company shall provide a pest sighting log or reporting system to be maintained in a designated area for food facility staff to alert the pest management professional of pests found. The log can include dates, times, locations, type of pest, action taken and name of reporting employee. The log must be reviewed by the technician at each visit and actions taken recorded. The use of the log should be discussed with facility staff during pest management training performed by the pest management professional or an in-house trainer.

4.4 LICENSES AND CERTIFICATES

Current credentials must be available with the pest management records and must include:

- Copy of the certification or registration document, if issued in the facility jurisdiction, for each person who will perform pest management services in the facility
- Copy of the pest management company license to operate issued by the state or provincial lead pesticide enforcement agency if issued by the state or province in the jurisdiction.
- Copy of the insurance certificate
- Copy of proof of successful completion of verifiable food facility pest management training and exam for each technician servicing the facility.

4.5 SERVICE PROTOCOLS AND STANDARD OPERATING PROCEDURES

Standard Operating Procedures shall be developed in partnership between the pest management company and the food facility. All scope of work information including methods of inspection and treatment must be documented and approved by the food facility. Protocols and procedures shall include at least the following:

- Procedures for all current or anticipated pest management activities including inspections and audits
- Pest sighting log
- Pest activity records
- Treatment Records (see 4.6 for minimum information required)
- Trend reports
- Facility map with pest management equipment listed such as rodent stations, monitoring devices, etc.

4.6 SERVICE AND TREATMENT RECORDS

All service records for service including applications and/or monitoring shall include:

- EPA or PMRA registration number
- Product brand name
- Target pest
- Rate of application or % concentration
- Time of application
- Location or site of application
- Amount of finished product used
- Date
- Signature of technician
- Signature of facility contact
- Certification or registration number of technician
- Notes and observations and any other records required by the governmental pest management enforcement agency, facility or third party audit program.

SECTION 5

NATIONAL ORGANIC PROGRAM

5.1 WORKING IN NOP FACILITIES

Organic is a labeling term that indicates that the food or other agricultural products have been produced through approved methods as well as facilities that produce, manufacture or store and distribute organic products. The organic standards describe the specific requirements that must be verified by a USDA-accredited certifying agent (auditor) before products can be labeled USDA organic.

Overall, all organic operations must demonstrate that they are protecting natural resources, conserving biodiversity, and using only approved substances.

The USDA National Organic Program is governed by Rule 205.271 and requires the handler or management of the organic facility to use management practices to prevent pests. While many of the physical prevention methods are beyond the scope of the pest management company, the NOP records will work with the pest management program to ensure that there is compliance with Rule 205.271 (example below). The NOP does not prevent the use of pest management methods or products; however, the NOP does require that pest prevention is done through mechanical or physical management and/or natural or approved traps and repellents. If these measures fail to manage the pests, the facility may use a natural substance approved by the organic certifying body, and if that fails, then a synthetic substance may be used “provided that the handler and the certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.” The NOP requires full attention to IPM. The facility may have specialized rules governing pest management activities in the facility. Please verify with all requirements of the facility before beginning service.

In addition to the standards in sections one through four, the NOP facilities will require the Standard Operating Procedures (SOPs) to prioritize pest management methods based on the information above. The company shall work with the facility to make sure that the procedures and SOPs comply with the facility SOPs regarding pest management. See federal government publications for more information.

Note: some organic facilities are audited by a certification group which may have approved methods or products. The facility should be consulted as to special requirements.

Procedures to ensure that the equipment, facility and food will not be contaminated by any pest management method must be in place prior to beginning any service.

As with all Pest Management Plans documentation is the key for success not only for the pest management company but also more importantly the protection and integrity of your customer’s organic certification.

The following is taken directly from the USDA National Organic Plan

205.271 FACILITY PEST MANAGEMENT PRACTICE STANDARD.

- (a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:
 - (1) Removal of pest habitat, food sources, and breeding areas;
 - (2) Prevention of access to handling facilities; and
 - (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.
- (b) Pests may be controlled through:
 - (1) Mechanical or physical controls including but not limited to traps, light, or sound; or
 - (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List. See section
- (c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.
- (d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: *Provided*, that, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.
- (e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.
- (f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations: *Provided*, that, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

APPENDIX A | PEST MANAGEMENT INSPECTION REPORT

Inspector _____ Date _____

		CORRECTIONS		
		OK	Req'd	N/A
EXTERIOR AREAS (including roof areas)	1. No evidence of pest activity			
	2. No pest harborage areas			
	3. Adequate trash handling			
	4. Proper trash containers			
	5. All trash contained			
	6. Proper storage of waste paper and cardboard			
	7. Pavement areas in good repair and properly drained			
	8. Adequate weed management adjacent to building			
	9. Adequate exterior rodent management program			
	10. Adequate exterior insect management program			
	11. No evidence of bird roosting			
	12. Sufficient cleaning capabilities to prevent buildup of food which may attract pests (e.g. flour spills at railroad offloading, corn syrup spills from trucks, etc.)			
	13. No evidence of plumbing or sewer leaks			
	14. Screens and vents clean			
	15. Open doors and windows screened			
	16. Visible condensate lines clear and clean			
INTERIOR AREAS	1. Walls: Clean, proper materials, and in good repair			
	2. Floors: Clean, proper materials, and in good repair			
	3. Ceilings: Clean, proper materials, and in good repair			
	4. Elevator pits clean and dry			
	5. Floor drains clean with secured covers			
	6. Plumbing in good repair as related to pest potential			
	7. Visible condensate lines clear and no pooling of condensate			
	8. Other maintenance issues			
	9. No evidence of pest activity			
	10. Inspection aisles properly maintained			
	11. Other practices issues			
	12. Packaging material properly stored			
	13. Containers properly stored and clean			
	14. Damaged/returned good isolated			
	15. Equipment clean and pest free			
	16. Maintenance areas clean and no evidence of pests			
	17. Sanitation area clean and no evidence of pests; mops and tools stored off floor			
	18. Compliance with pest portion of GMPs			
	19. Pest management equipment clean and maintained (e.g. light traps, etc.)			

Technician _____ Date _____

Comments _____

Signature of Technician _____

APPENDIX B | SAMPLE RISK ASSESSMENT

Risks assessments should be conducted to identify current or potential pest problems within food processing and handling facilities. A risk assessment is an interactive process that includes a close examination of the entire property and existing documentation. Risk assessments are only one component of a successful integrated pest management plan which also includes proper implementation, management and communication.

This “sample risk assessment” is meant to be used as a tool to assist in analyzing, creating and maintaining a successful pest management in food processing and handling facilities plan. The sample risk assessment does not provide an exhaustive list of potential pest problems but merely a starting point. Additionally, each facility is unique which may present entirely different considerations and potential pest problems.

The 2016 Pest Management Standards for Food Processing and Handling Facilities does NOT require the use of this risk assessment but has included this document as a reference point to identify factors that should be considered when conducting risk assessments and then implementing a successful integrated pest management plan.

SAMPLE RISK ASSESSMENT

ASSESSMENT DATE _____

PERFORMED BY _____

TITLE _____

FACILITY NAME _____

FACILITY ADDRESS _____

PRINCIPAL CONTACTS

FACILITY TYPE	<input type="checkbox"/> Processing	<input type="checkbox"/> Storage	<input type="checkbox"/> Packaging	<input type="checkbox"/> Other
REPORT TYPE	<input type="checkbox"/> Baseline	<input type="checkbox"/> Quarterly	<input type="checkbox"/> Annually	<input type="checkbox"/> Other
SCORING KEY	L M H NA	(Low) (Moderate) (High) (Not Applicable)	Prevention of pest infestation recommendation Probable or potential pest infestation risk Imminent pest infestation risk	

LOG BOOK: REVIEW THE TREND ANALYSIS OR PEST ACTIVITY CHARTS	L	M	H	N/A
1. Rodent activity is decreasing (L), remaining the same (M), or continuing to increase (H).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Insect and other arthropod pest activities are decreasing (L), remaining the same (M), or continuing to increase (H).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EXTERIOR AREAS	L	M	H	N/A
3. There is a risk of unmaintained weeds, grass and brush in areas around the facility to harbor pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. There is a risk of weeds or other material along the fence line permitting rodent harborage.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. There is a risk of rodents burrowing around the perimeter of the building (maintain a 2-foot pea gravel strip around the building to discourage rodents from burrowing in these areas).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk of standing water on the building grounds to attract pests (i.e., mosquitoes, geese, small rodents, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk of spillage, exposure or accumulation of waste in garbage containment area.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. There is a risk of fly infestations in the garbage containment area.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. There is a risk of pest entry through gaps under or around exit doors (a gap equal or greater than 1/4" in diameter allows the entry of mice and arthropods).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. There is a risk of pest entry through broken, open or unscreened windows/vents.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. There is a risk of pest entry through holes, cracks and crevices near window and door frames or in the exterior walls.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. There is a risk of pest entry around plumbing and electrical service pipes and lines.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. There is a risk of pests hiding in holes, cracks and crevices in the exterior walls.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. There is a risk of birds nesting or roosting in the buildings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. There is a risk of feeding or nesting geese in exterior grounds.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. There is a risk of rodent harborage on the building grounds.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. There is a risk of equipment and material stored near the building to provide harborage for pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. There is a risk of fluorescent lights used on or near the building to attract night-flying insects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. There is a risk of rodent entry on railroad siding doors.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. There is a risk of inadequate number of perimeter rodent stations to ensure control of rodents.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PRINCIPAL CONTACTS

FACILITY TYPE	<input type="checkbox"/> Processing	<input type="checkbox"/> Storage	<input type="checkbox"/> Packaging	<input type="checkbox"/> Other
REPORT TYPE	<input type="checkbox"/> Baseline	<input type="checkbox"/> Quarterly	<input type="checkbox"/> Annually	<input type="checkbox"/> Other
SCORING KEY	L	(Low)	Prevention of pest infestation recommendation	
	M	(Moderate)	Probable or potential pest infestation risk	
	H	(High)	Imminent pest infestation risk	
	NA	(Not Applicable)		

INTERIOR & STORAGE AREAS	L	M	H	N/A
21. There is a risk of holes or cracks in the walls to provide pests with hiding sites.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. There is a risk of gaps around the platform floor/wall junction and ceiling/walls junction to provide pests with hiding and breeding sites.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. There is a risk of dirty drains to provide pests with breeding sites.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. There is a risk of missing or cracked floor grouting or tiles to provide accumulation of water or debris.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. There is a risk of standing water to attract pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. There is a risk of inadequate number of pheromone traps in the facility to monitor insect activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. There is a risk of inadequate number of rodent equipment in the facility to monitor and manage rodent activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. There is a risk of inadequate number of Insect Light Traps (ILTs) in the facility to monitor flying insect activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. There is a risk of inadequate storage practices of products (i.e., no 18" sanitary aisle along all interior walls, products are stored directly on the floor and not elevated off the ground on pellets, etc.). Inadequate storage of products can prevent pest monitoring and inspection practices, prevent proper cleaning of food spillage, and provide inaccessible hiding places for pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. There is a risk of broken or exposed products to attract pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. There is a risk of food spillage to attract pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. There is a risk of interior populations of stored product insects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. There is a risk of interior populations of ants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. There is a risk of interior populations of flies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. There is a risk of interior populations of cockroaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. There is a risk of interior populations of occasional invaders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. There is a risk of interior populations of rodents.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. There is a risk of interior populations of birds.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. There is a risk of interior populations of spiders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. There is a risk of food debris on top of product, equipment, along walls, etc. to provide pests with food.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. There is a risk of objectionable odors to attract pests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PRINCIPAL CONTACTS

FACILITY TYPE	<input type="checkbox"/> Processing	<input type="checkbox"/> Storage	<input type="checkbox"/> Packaging	<input type="checkbox"/> Other
REPORT TYPE	<input type="checkbox"/> Baseline	<input type="checkbox"/> Quarterly	<input type="checkbox"/> Annually	<input type="checkbox"/> Other
SCORING KEY	L	(Low)	Prevention of pest infestation recommendation	
	M	(Moderate)	Probable or potential pest infestation risk	
	H	(High)	Imminent pest infestation risk	
	NA	(Not Applicable)		

RECEIVING & SHIPPING AREAS	L	M	H	N/A
42. There is a risk of pest infestation in the carrier vehicles (dirty and unmaintained carrier vehicles will provide pests with food and hiding places).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. There is a risk of pest introductions due to an inadequate incoming rodent/insect inspection procedures for all incoming products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. There is a risk of pest breeding sites underneath uncleaned dock levelers.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. There is a risk of pest entry through dock doors left open when not in use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. There is a risk of accumulations of over-aged products to attract pests (products that are received first, should be used or shipped first (FIFO; First in-First out).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47. There is a risk of accumulations of empty cartons and cases to attract pests for hiding.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DINING ROOMS, LOCKER ROOM & OFFICE AREAS	L	M	H	N/A
48. The risk of pests to be introduced from these areas due to: accumulations of food debris, clutter on tops of the lockers and vending machines, employees unintentionally bringing pests from their homes, lack of pest monitoring devices, leaky water pipes, lack of self-closing doors between these areas and the production areas, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

OVERALL COMMENTS/OBSERVATIONS

PLEASE USE THIS SECTION TO PROVIDE COMMENTS AND/OR OBSERVATIONS TO SUPPLEMENT THE INFORMATION PROVIDED ABOVE OR TO PROVIDE ADDITIONAL INFORMATION AND OTHER POTENTIAL PEST PROBLEMS

1.

2.

3.

4.

5.

6.

7.

8.

9.

10.

11.

SCORING

THIS SCORING IS NOT INTENDED TO BE AN ABSOLUTE SCORE. THE SCORE IS BEST USED RELATIVE TO PAST AND FUTURE AUDITS, IN ORDER TO ANSWER THE QUESTION, ARE YOU IMPROVING?

1. Calculate the % of low, moderate and high using the following formula:

% LOW: $\text{Total Low Responses} / (\text{Total Inspected items (48)} - \text{N/A Responses}) \times 100 =$ _____

% MODERATE: $\text{Total Moderate Responses} / (\text{Total Inspected items (48)} - \text{N/A Responses}) \times 100 =$ _____

% HIGH: $\text{Total High Responses} / (\text{Total Inspected items (48)} - \text{N/A Responses}) \times 100 =$ _____

2. Compare the % of low, moderate and high and select the best course of actions to reduce risks.

RECOMMENDATIONS

EXTERIOR

#	OBSERVATIONS	RECOMMENDED SOLUTION

INTERIOR & STORAGE AREAS

#	OBSERVATIONS	RECOMMENDED SOLUTION

RECEIVING & SHIPPING AREAS

#	OBSERVATIONS	RECOMMENDED SOLUTION

DINING ROOM, LOCKER ROOMS & OFFICE AREAS

#	OBSERVATIONS	RECOMMENDED SOLUTION

MISCELLANEOUS

#	OBSERVATIONS	RECOMMENDED SOLUTION

APPENDIX C | CURRENT GOOD MANUFACTURING PRACTICES, 21 C.F.R. §117

Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

SUBPART A GENERAL PROVISIONS

- §117.1 Applicability and status.
- §117.3 Definitions.
- §117.4 Qualifications of individuals who manufacture, process, pack, or hold food.
- §117.5 Exemptions.

SUBPART B CURRENT GOOD MANUFACTURING PRACTICE

- §117.10 Personnel.
- §117.20 Plant and grounds.
- §117.35 Sanitary operations.
- §117.37 Sanitary facilities and controls.
- §117.40 Equipment and utensils.
- §117.80 Processes and controls.
- §117.93 Warehousing and distribution.
- §117.95 Holding and distribution of human food by-products for use as animal food.
- §117.110 Defect action levels.

SUBPART C HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

- §117.126 Food safety plan.
- §117.130 Hazard analysis.
- §117.135 Preventive controls.

SUBPART A GENERAL PROVISIONS

§117.1 APPLICABILITY AND STATUS.

- (a) The criteria and definitions in this part apply in determining whether a food is:
 - (1) Adulterated within the meaning of:
 - (i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or
 - (ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and
 - (2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
- (b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, F, or G of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.
- (c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2015]

§117.3 DEFINITIONS.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Correction means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm means farm as defined in §1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into

a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by §117.180(c)(2). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in §1.227 of this chapter) that:

- (1) Is located:
 - (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
 - (ii) Not more than 275 miles from such facility; and
- (2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

- (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

- (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under §117.5(a).

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged food means packaged food that is not exposed to the environment.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Written procedures for receiving raw materials and other ingredients means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3715, Jan. 22, 2015]

EFFECTIVE DATE NOTE: At 80 FR 56145, Sept. 17, 2015, §117.3 was added, effective Nov. 16, 2015, except for paragraph (2) of the definition of “qualified auditor”. FDA will publish a document in the FEDERAL REGISTER announcing the effective date for this paragraph.

§117.4 QUALIFICATIONS OF INDIVIDUALS WHO MANUFACTURE, PROCESS, PACK, OR HOLD FOOD.

(a) *Applicability.*

- (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.
- (2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.

(b) *Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.* Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

- (1) Be a qualified individual as that term is defined in §117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
- (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

- (d) *Records.* Records that document training required by paragraph (b)(2) of this section must be established and maintained.

§117.6 EXEMPTIONS.

- (a) Except as provided by subpart E of this part, subparts C and G of this part do not apply to a qualified facility. Qualified facilities are subject to the modified requirements in §117.201.
- (b) Subparts C and G of this part do not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if you are required to comply with, and are in compliance with, part 123 of this chapter with respect to such activities.
- (c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities.
- (d) (1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities.
- (2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.
- (e) Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).
- (f) Subparts C and G of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- (g) (1) The exemption in paragraph (g)(3) of this section applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the “farm” definition in §1.227 of this chapter. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.
- (2) For the purposes of paragraphs (g)(3) and (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (*i.e.*, coffee beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.
- (i) *Dried/dehydrated fruit and vegetable products* includes only those processed food products such as raisins and dried legumes made without additional

manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

- (ii) *Other fruit and vegetable products* includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (g)(2)(i) of this section. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).
 - (iii) *Peanut and tree nut products* includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.
 - (iv) *Processed seeds for direct consumption* include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.
 - (v) *Dried/dehydrated herb and spice products* includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.
 - (vi) *Other herb and spice products* includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph (g)(2)(v) of this section. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.
 - (vii) *Grains* include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).
 - (viii) *Milled grain products* include processed food products such as flour, bran, and corn meal.
 - (ix) *Baked goods* include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.
 - (x) *Other grain products* include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (g)(2)(viii) of this section or baked goods as described in paragraph (g)(2)(ix) of this section.
- (3) Subparts C and G of this part do not apply to on-farm packing or holding of food by a small or very small business, and §117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations — *i.e.*, packing

(or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- (xi) Baked goods (e.g., bread and cookies);
- (xii) Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
- (xiii) Cocoa beans (roasted);
- (xiv) Cocoa products;
- (xv) Coffee beans (roasted);
- (xvi) Game meat jerky;
- (xvii) Gums, latexes, and resins that are processed foods;
- (xviii) Honey (pasteurized);
- (xix) Jams, jellies, and preserves;
- (xx) Milled grain products (e.g., flour, bran, and corn meal);
- (xxi) Molasses and treacle;
- (xxii) Oils (e.g., olive oil and sunflower seed oil);
- (xxiii) Other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
- (xxiv) Other grain products (e.g., dried pasta, oat flakes, and popcorn);
- (xxv) Other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);
- (xxvi) Peanut and tree nut products (e.g., roasted peanuts and tree nut flours);
- (xxvii) Processed seeds for direct consumption (e.g., roasted pumpkin seeds);
- (xxviii) Soft drinks and carbonated water;
- (xxix) Sugar;
- (xxx) Syrups (e.g., maple syrup and agave syrup);
- (xxxi) Trail mix and granola;
- (xxxii) Vinegar; and
- (xxxiii) Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

- (h) (1) The exemption in paragraph (h)(3) of this section applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the “farm” definition in §1.227 of this chapter. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition in §1.227 of this chapter. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject

to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

- (2) The terms in paragraph (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (h)(3) of this section.
- (3) Subparts C and G of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and §117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk manufacturing/processing activity/food combinations:
 - (i) Boiling gums, latexes, and resins;
 - (ii) Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);
 - (iii) Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));
 - (iv) Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea);
 - (v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh mint, chopped dried mint);
 - (vi) Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables);
 - (vii) Grinding/cracking/crushing/milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);

- (viii) Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- (ix) Making baked goods from milled grain products (e.g., breads and cookies);
- (x) Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy toffee), and saps (e.g., maple candy, maple cream);
- (xi) Making cocoa products from roasted cocoa beans;
- (xii) Making dried pasta from grains;
- (xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
- (xiv) Making molasses and treacle from sugar beets and sugarcane;
- (xv) Making oat flakes from grains;
- (xvi) Making popcorn from grains;
- (xvii) Making snack chips from fruits and vegetables (e.g., making plantain and potato chips);
- (xviii) Making soft drinks and carbonated water from sugar, syrups, and water;
- (xix) Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
- (xx) Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;
- (xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g. fruit wines, apple cider), and other grain products (e.g., malt);
- (xxii) Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact

- oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g. bone meal) in powdered, granular, or other solid form);
- (xxiii) Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g. bone meal) in powdered, granular, or other solid form);
 - (xxiv) Pasteurizing honey;
 - (xxv) Roasting and toasting baked goods (e.g., toasting bread for croutons);
 - (xxvi) Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and
 - (xxvii) Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).
- (i) (1) Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:
 - (i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and
 - (ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.
 - (2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, provided such food:
 - (iii) Is in prepackaged form that prevents any direct human contact with such food; and
 - (iv) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.
 - (j) Subparts C and G of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

- (k) (1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:
- (i) "Farms" (as defined in §1.227 of this chapter);
 - (ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this chapter in accordance with §1.226(f) of this chapter;
 - (iii) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;
 - (iv) Activities of "farm mixed-type facilities" (as defined in §1.227 of this chapter) that fall within the definition of "farm"; or
 - (v) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).
- (2) If a "farm" or "farm mixed-type facility" dries/dehydrates raw agricultural commodities that are produce as defined in part 112 of this chapter to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2015]

SUBPART B CURRENT GOOD MANUFACTURING PRACTICE

§117.10 PERSONNEL.

The management of the establishment must take reasonable measures and precautions to ensure the following:

- (a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.
- (b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:
 - (1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.
 - (2) Maintaining adequate personal cleanliness.
 - (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 - (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
 - (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.
 - (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
 - (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
 - (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
 - (9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§117.20 PLANT AND GROUNDS.

- (a) *Grounds.* The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:
- (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.
 - (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
 - (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
 - (4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
 - (5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.
- (b) *Plant construction and design.* The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:
- (1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.
 - (2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.
 - (3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:
 - (i) Using protective coverings.
 - (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
 - (iii) Checking on a regular basis for pests and pest infestation.
 - (iv) Skimming fermentation vessels, as necessary.
 - (4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.
 - (5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light

bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

- (6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.
- (7) Provide, where necessary, adequate screening or other protection against pests.

§117.35 SANITARY OPERATIONS.

- (a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.
- (b) *Substances used in cleaning and sanitizing; storage of toxic materials.*
 - (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
 - (i) Those required to maintain clean and sanitary conditions;
 - (ii) Those necessary for use in laboratory testing procedures;
 - (iii) Those necessary for plant and equipment maintenance and operation; and
 - (iv) Those necessary for use in the plant's operations.
 - (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- (c) *Pest control.* Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.
- (d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.
 - (1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

- (2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.
 - (3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.
- (e) *Sanitation of non-food-contact surfaces.* Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.
- (f) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§117.37 SANITARY FACILITIES AND CONTROLS.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

- (a) *Water supply.* The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
- (b) *Plumbing.* Plumbing must be of adequate size and design and adequately installed and maintained to:
- (1) Carry adequate quantities of water to required locations throughout the plant.
 - (2) Properly convey sewage and liquid disposable waste from the plant.
 - (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
 - (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
 - (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.
- (c) *Sewage disposal.* Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

- (d) *Toilet facilities.* Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.
- (e) *Hand-washing facilities.* Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.
- (f) *Rubbish and offal disposal.* Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§117.40 EQUIPMENT AND UTENSILS.

- (g) (1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
- (2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
- (3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
- (4) Food-contact surfaces must be corrosion-resistant when in contact with food.
- (5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
- (6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.
- (h) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.
- (i) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.
- (j) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.
- (k) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

- (l) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.
- (m) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§117.80 PROCESSES AND CONTROLS.

(a) *General.*

- (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
- (2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
- (3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
- (4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
- (5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
- (6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) *Raw materials and other ingredients.*

- (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.
- (2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.
- (3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.
- (4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

- (5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.
 - (6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.
 - (7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.
 - (8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.
- (c) *Manufacturing operations.*
- (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.
 - (2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
 - (3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
 - (4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.
 - (5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
 - (6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
 - (7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
 - (8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
 - (9) Food, raw materials, and other ingredients that are adulterated:
 - (i) Must be disposed of in a manner that protects against the contamination of other food; or
 - (ii) If the adulterated food is capable of being reconditioned, it must be:
 - (A) Reconditioned (if appropriate) using a method that has been proven to be effective; or

- (B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.
- (10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.
- (11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
- (12) Batters, breadings, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.
- (13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
- (14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.
- (15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.
- (16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with §117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§117.93 WAREHOUSING AND DISTRIBUTION.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§117.95 HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD.

- (a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

- (1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
 - (2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
 - (3) During holding, human food by-products for use as animal food must be accurately identified.
- (b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.
 - (c) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

[80 FR 56337, Sept. 17, 2015]

§117.110 DEFECT ACTION LEVELS.

- (a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at www.fda.gov/pchfrule and at www.fda.gov.

SUBPART C HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

§117.126 FOOD SAFETY PLAN.

- (a) *Requirement for a food safety plan.*
 - (1) You must prepare, or have prepared, and implement a written food safety plan.
 - (2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.
- (b) *Contents of a food safety plan.* The written food safety plan must include:
 - (1) The written hazard analysis as required by §117.130(a)(2);
 - (2) The written preventive controls as required by §117.135(b);
 - (3) The written supply-chain program as required by subpart G of this part;
 - (4) The written recall plan as required by §117.139(a); and
 - (5) The written procedures for monitoring the implementation of the preventive controls as required by §117.145(a)(1);
 - (6) The written corrective action procedures as required by §117.150(a)(1); and
 - (7) The written verification procedures as required by §117.165(b).
- (c) *Records.* The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§117.130 HAZARD ANALYSIS.

- (a) *Requirement for a hazard analysis.*
 - (1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.
 - (2) The hazard analysis must be written regardless of its outcome.
- (b) *Hazard identification.* The hazard identification must consider:
 - (1) Known or reasonably foreseeable hazards that include:
 - (i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
 - (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
 - (iii) Physical hazards (such as stones, glass, and metal fragments); and
 - (2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:
 - (i) The hazard occurs naturally;

- (ii) The hazard may be unintentionally introduced; or
- (iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.*

- (1) (i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- (ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
- (2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
 - (i) The formulation of the food;
 - (ii) The condition, function, and design of the facility and equipment;
 - (iii) Raw materials and other ingredients;
 - (iv) Transportation practices;
 - (v) Manufacturing/processing procedures;
 - (vi) Packaging activities and labeling activities;
 - (vii) Storage and distribution;
 - (viii) Intended or reasonably foreseeable use;
 - (ix) Sanitation, including employee hygiene; and
 - (x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

§117.135 PREVENTIVE CONTROLS.

- (a) (1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
- (2) Preventive controls required by paragraph (a)(1) of this section include:
 - (i) Controls at critical control points (CCPs), if there are any CCPs; and
 - (ii) Controls, other than those at CCPs, that are also appropriate for food safety.
- (b) Preventive controls must be written.
- (c) Preventive controls include, as appropriate to the facility and the food:
 - (1) *Process controls.* Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- (i) Parameters associated with the control of the hazard; and
 - (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.
- (2) *Food allergen controls.* Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:
 - (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
 - (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
- (3) *Sanitation controls.* Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:
 - (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
 - (ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.
- (4) *Supply-chain controls.* Supply-chain controls include the supply-chain program as required by subpart G of this part.
- (5) *Recall plan.* Recall plan as required by §117.139.
- (6) *Other controls.* Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.



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